GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2656
ANSWERED ON:10.08.2005
RESTRICTIONS ON DRUG IMPORTERS
Singh Shri Uday

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) Whether the Government has put certain restrictions on drug importers;

(b) if so, the details thereof?

(c) Whether the import of drugs under OGL without the Government`s clearance is not allowed;

(d) if so, whether the drug importers have violated the norms for the purpose; and

(e) if so, the action taken by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a)&(b): Yes, Sir. Under the provision of Drugs & Cosmetics Act and Rules framed thereunder no drug can be imported into the country without foreign drug manufacturing site registration alognwith their manufactured drugs and Import Licence in Form 10 under the said rules.

(c) to (e): Although, no drug can be imported without manufacturing site registration and Import Licence in Form 10 under the provisions of Drugs & Cosmetics Rules, certain exemptions have been given under the Drugs & Cosmetics Rules for import of drugs without registration certificate and Form 10 Licence in respect of the following:

1. Drugs imported against Advanced Licences being issued by Directorate General of Foreign Trade, (DGFT), Ministry of Commerce under ITC policy.

2. Small quantities of drugs imported for the purposes of clinical trials & for testing purposes.

3. Unapproved Bulk drugs imported for the purposes of meeting export commitments.

4. Drugs imported as donation/gift by various NGOs for the purposes of distribution to poor patients.

5. Very small quantities of drugs imported by a patient against a medical prescription for his/her own use.

6. Small quantities of drugs imported by an exporters for carrying out job work/value addition when the entire quantity is re exported.

7. Government Hospitals and Autonomous Institutions importing new drugs for the treatment of their own patients.

Any specific instance of reported violation is investigated as per the norms.